

Massachusetts Department of Public Health  
State Laboratory Institute  
305 South Street, Jamaica Plain, MA 02130  
Author: Margaret DiNatale

SOP: QA.004  
Version: 2  
Page 6 of 6  
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**Attachment #2 Coversheet for Reviewers SOP / Manufacturer Insert Comparison**

Using the attached form, compare the manufacturer's criteria with the criteria in the laboratory's SOP. If all criteria match, circle "match" for the item. If there is a difference, circle "differences". For any difference, write a brief comment or corrective action below that item. If the test is from the LRN or CDC, please use those documents as the reference documents.

The manufacturer package inserts and Laboratory SOPs have been reviewed.

Paul Elkin 4/6/11  
Laboratory Supervisor / Date

Comments:

Wendy S. Smith 4/11/11  
Laboratory Director / Date

Comments:

Tracy Stohs 4/11/11  
Quality Assurance Director or Manager / Date

Comments:

Attachment #1 Comparison Documentation Grid

SOP Title / number: <i>MTD</i>	Reviewed by / date: <i>PE 4/6/11</i>		
Specimen requirements	QC	Linearity or reportable range	
Specimen type <i>match</i> differences	Material: <i>match</i> differences	Method reportable limits: <i>match</i> differences	
Unacceptable spec.: <i>match</i> differences	Acceptance Criteria: <i>match</i> differences	Processing specimens above upper reportable limit: <i>match</i> differences	
Testing limitations: coll date to test date transportation storage prior to testing	match differences		
SOP Title / number: <i>MGT 960</i>	Reviewed by / date: <i>PE 4/6/11</i>		
Specimen requirements	QC	Linearity or reportable range	
Specimen type <i>match</i> differences	Material: <i>match</i> differences	Method reportable limits: <i>match</i> differences	
Unacceptable spec.: <i>match</i> differences	Acceptance Criteria: <i>match</i> differences	Processing specimens above upper reportable limit: <i>match</i> differences	
Testing limitations: coll date to test date transportation storage prior to testing	match differences		
SOP Title / number: <i>Quant, team 6010</i>	Reviewed by / date: <i>PE 4/6/11</i>		
Specimen requirements	QC	Linearity or reportable range	
Specimen type <i>match</i> differences	Material: <i>match</i> differences	Method reportable limits: <i>match</i> differences	
Unacceptable spec.: <i>match</i> differences	Acceptance Criteria: <i>match</i> differences	Processing specimens above upper reportable limit: <i>match</i> differences	
Testing limitations: coll date to test date transportation storage prior to testing	match differences		

Attachment #1 Comparison Documentation Grid

SOP Title / number: <i>Back SIRE Testing</i>			Reviewed by / date: <i>PE 4/6/11</i>
<b>Specimen requirements</b>  Specimen type <u>match</u> differences Unacceptable spec.:      match      differences Testing limitations: coll date to test date      match      differences transportation      match      differences storage prior to testing      match      differences			<b>QC</b>  Material: <u>match</u> differences  Acceptance Criteria: <u>match</u> differences
			<b>Linearity or reportable range</b>  Method reportable limits: <u>match</u> differences
			Processing specimens above upper reportable limit: match      differences
SOP Title / number: <i>MGRT 960 PZA</i>			Reviewed by / date: <i>PE 4/6/11</i>
<b>Specimen requirements</b>  Specimen type <u>match</u> differences Unacceptable spec.:      match      differences Testing limitations: coll date to test date      match      differences transportation      match      differences storage prior to testing      match      differences			<b>QC</b>  Material: <u>match</u> differences  Acceptance Criteria: <u>match</u> differences
			<b>Linearity or reportable range</b>  Method reportable limits: <u>match</u> differences
			Processing specimens above upper reportable limit: match      differences
SOP Title / number: <i>Acc. probe testing</i>			Reviewed by / date: <i>PE 4/6/11</i>
<b>Specimen requirements</b>  Specimen type <u>match</u> differences Unacceptable spec.: <u>match</u> differences Testing limitations: coll date to test date      match      differences transportation      match      differences storage prior to testing      match      differences			<b>QC</b>  Material: <u>match</u> differences  Acceptance Criteria: <u>match</u> differences
			<b>Linearity or reportable range</b>  Method reportable limits: <u>match</u> differences
			Processing specimens above upper reportable limit: match      differences